

REMARKS

Reconsideration of the pending claims based on the amendments and remarks presented herewith, is respectfully requested.

Claims 1, 2, 4-6, 9-11, 35, and 39-44 are pending. Claims 7, 8, 38, and 45 have been canceled. Claims 24-34 and 46-47 have been canceled without prejudice to their future prosecution.

Claims 2, 4-6, and 44 have been amended. No new matter is added with the amendments.

Rejections under 35 U.S.C. § 112(1).

The Examiner rejected Claims 1, 2, 4-11, 35 and 38-45 under Section 112(1) for lack of enablement. This rejection is respectfully traversed.

The Examiner acknowledges the specification is enabling for a method of increasing and/or decreasing blood flow to the vagina by inhaling particular commercial odorants or mixtures thereof. However, the Examiner maintains that the specification is not enabling for a method by inhaling any "*undefined odorant*" other than one of the particular listed commercial odorants or mixtures. The Examiner maintains that the instantly claimed odorants are highly subjective with respect to the actual odors being encompassed, giving a recipe of pumpkin pie or banana nut bread -which can vary according to the ingredients - as evidence that the odors emitted would be speculative based on a particular recipe.

First of all, it is noted that the claims have been amended to particular odorant mixtures.

It is respectfully submitted that Applicant's disclosure is fully enabling for odorants manufactured by other sources than those provided. According to Section 112, an Applicant is required to teach how to use an invention, and it is well settled that it is not necessary that the specification disclose every operative example when one skilled in the art is fully apprised by the disclosure of what the invention is and how to use it. A disclosure that contains representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of the claim will possess the described utility is all that is required. It is respectfully submitted that the nature of the recited odorants is not ambiguous to one skilled in the odorants arts and would be readily ascertainable.

Applicant has provided sources of commercial odorants, which are exemplary, from which one skilled in the odorant arts would be able to readily identify suitable odorants from other sources - both synthetic (commercially prepared) and natural sources (e.g., essential oils) - that have the recited odorant characteristic to formulate the recited odorant mixture that would achieve the desired effect to alter blood flow to the vagina when inhaled by a female individual. As recited in the claims, suitable odorant mixtures are those having the recited characteristic of a mixture of: a) a licorice-based odorant and banana nut bread odorant, b) a licorice-based odorant and a cucumber odorant, c) a lavender odorant and a pumpkin pie odorant, and d) a baby powder odorant and a chocolate odorant.

It is well known in the art to utilize such methods as gas chromatography-mass spectrometry (GC-MS). among others, to determine the aroma components of an odorant compound. A gas chromatograph distinguishes compounds by comparing to a reference standard. The Examiner is respectfully directed to the following enclosed examples of Abstracts that address the identification of aroma components that contribute to various odorants: Jordan et al., "Aromatic profile of aqueous banana essence and banana fruit by gas chromatography-mass spectrometry (GC-MS) and gas chromatography-olfactometry (GC-O)," *J. Agric. Food Chem.* 49(10):4813-7 (2001); Zhou et al., Identification and quantification of aroma-active components that contribute to the distinct malty flavor of buckwheat honey," *J. Agric. Food Chem.* 50(7): 2016-21 (2002). See also, Hamilton et al., "Measuring Farmstead Odors," Oklahoma Cooperative Extension Service, OSU Extension Facts F-1740 (06-1999), at (<http://agweb.okstate.edu/pearl/biosystems/general/f1740.htm>) which discusses the use of a gas chromatograph with a mass spectrometer detector in odorant analysis. See also, *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985) at page 844, which discusses the use of instrumental techniques to separate and identify volatile organic substances, for example, capillary gas chromatography columns in tandem with a mass spectrometer, Fourier transform nmr spectroscopy.

Those of ordinary skill in the art of odor science would utilize such instruments as a gas chromatograph with a mass spectrometer detector to prepare an odorant such as a licorice-based odorant, banana nut bread odorant, and so forth, according to an established quality - which in the present application can be ascertained by utilizing the described commercial source odorants

as a basis, for example. The particular odor ingredients of such odorants mixtures would not vary as a recipe as the Examiner contends, but would possess a particular "accord" (or "theme") based on particular "notes" according to the particular odorant.

The characteristics of the odorants in the mixtures recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorant mixtures from various sources that have the recited odorant character and would achieve the desired effect of altering blood flow to the vagina when inhaled by a female individual.

Furthermore, natural sources of the odorants can be utilized in Applicant's method. As disclosed in the specification at page 4, lines 16-19, odorants can be utilized from commercial sources and as essential oils (i.e., volatile material isolated from a plant source), for example. See, enclosed pages 810-811 from *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985) discussing essential oils. For example, a natural source of lavender are flowers of *Lavandula spica* (*Ilavandula officinalis* or *Lavandula vera*) which contains a volatile oil with the principal constituent *l*-linalyl acetate. A natural source of licorice can be derived the dried rhizome and roots of *Glycyrrhiza glabra* L., *G. glabra* L. var. *glandulifera*, or other varieties. See, *The Merck Index*, 11th Ed., Entry 5261 (lavender) and Entry 4400 (glycyrrhiza), Merck & Co., Inc. (1989); *Remington's Pharmaceutical Sciences*, 18th Ed., Mack Publishing Co., Easton, Pennsylvania (1990) at pages 1294 and 1300. Natural sources of odorants are well known in the art.

Furthermore, satisfaction of the enablement requirement of Section 112 is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Jackson*, 217 USPA 804 (Bd. App. 1982).

The character of the particular odorants recited in the claims is well-delineated, commercial source odorants are identified, and a working example is provided that would enable an art worker to obtain and employ such compounds as broadly as they are claimed, particularly based on the knowledge in the odorant arts.

The Examiner is also directed to Applicant's issued patents as evidence of enablement and the understanding in the art, with claims directed to various odorants (i.e., *mixture of lavender and pumpkin pie*, green apple, peppermint, banana, floral, barbecue smoke, etc.), for which examples of commercial sources were provided:

USP 6,106, 837 with claims to a method and article of manufacture for treating headaches, reciting odorants (Claim 1: green apple, Claim 28: peppermint, banana) and providing a commercial source for the odorants in the specification at col. 3, lines 31-37.

USP 5,904,916 with claims to a method and article of manufacture for enhancing learning, recited odorants (Claim 1: floral odorant), and providing a commercial source for the odorants in the specification at col. 2, lines 6-9.

USP 5,885,614 with claims to a method and article of manufacture for increasing penile blood flow in a male individual, reciting odorants (Claims 1-3, etc., including a *mixture of lavender and pumpkin pie*), and providing a commercial source for odorants in the specification at col. 2, lines 40-43.

USP 5,759,521 with claims to a method of altering perception of relative space of an area, reciting odorants (Claim 1: green apple, Claim 10: barbecue smoke) and providing a commercial source for the odorants in the specification at col. 2, lines 45-47.

It is respectfully submitted that the odorants recited in the claims are clear in their meaning, and the present disclosure of commercial sources of those odorants and a working example is more than adequate to enable one of ordinary skill in this art area to carry out the invention commensurate with the scope of claims, as required under Section 112(1).

Based on Applicant's disclosure and the understanding in the art, it is submitted that the requirements under Section 112(1) have clearly been met in the present disclosure, and that an art worker in this area is fully enabled to practice Applicant's invention as broadly as it is claimed.

Accordingly, it is respectfully submitted that the claims fully comply with Section 112(1), and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §112(2).

The Examiner rejected the Claims 1, 2, 4-11 35 and 38-45 under Section 112(2) for the use of indefinite claim language.

The Examiner rejected Claim 10 on the basis that it is unclear as to what a 25-55 decismel unit concentration refers to. As stated in the specification at page 5, lines 4-7 (emphasis added):

...it is preferred that *the subject individual is presented with the odorant* at a superthreshold concentration (e.g., about 25-55 decismel units), but not irritative level,...

The Examiner further contends that the metes and bounds of the odorants recited in Claims 1, 2, 4-11 35 and 38-45 are not clearly delineated. The Examiner contends that the "subjective nature of the recited odorants (any of which is deemed essential in terms of adequately defining these particular active ingredients *in the claimed article of manufacture*) causes these claims to be very ambiguous and unclear." The Examiner maintains that the instantly claimed odorants are highly subjective with respect to the actual odors being encompassed, giving a recipe of pumpkin pie or banana nut bread -which can vary according to the ingredients - as evidence that the odors emitted would be speculative based on a particular recipe.

It is respectfully submitted that the nature of the recited odorants is not ambiguous to one skilled in the odorants arts and would be readily ascertainable.

The odorant characteristics of the odorants recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily identify suitable odorants from various sources that have the recited odorant character and would achieve the desired effect. As recited in the claims, suitable odorant mixtures are those having the recited characteristic of a mixture of: a) a *licorice*-based odorant and *banana nut bread* odorant, b) a *licorice*-based odorant and a *cucumber* odorant, c) a *lavender* odorant and a *pumpkin pie* odorant, and d) a *baby powder* odorant and a *chocolate* odorant, and are capable of altering blood flow to the vagina when inhaled by a female individual.

Further, the Examiner is directed to Applicant's issued patents, as described above, as evidence of definite claim language with respect to the listed odorants. Each of these issued patents claim various odorants (i.e., green apple, peppermint, banana, floral, barbecue smoke, mixture of lavender and pumpkin pie, etc.) for methods of treatment and articles of manufacture, for which examples of commercial sources were provided.

Based on that information, and the reasons stated above, it is respectfully submitted that, based on the present disclosure, is well within the understanding in the art to identify appropriate odorants for use in Applicant's invention. Accordingly, it is submitted that the claims are clear in their meaning and satisfy the requirements of Section 112(2), and withdrawal of this rejection is respectfully requested.

Rejection of Claims under 35 USC § 102(b)

The Examiner rejected Claims 5-11, 38 and 44 as anticipated by Doty (Philadelphia Sensorics, 1983) with evidence provided by Sweeney (USP 4,493,869) and the recognized state of the art. This rejection is respectfully traversed.

First of all, in the rejection, the Examiner asserted that the term "decismel units" "...appears to be a unit of measure seldom used in the odorant art other than by applicant..." (see, for example, the Office action at page 8).

The Examiner is respectfully directed to the following patent and publication indicating the use of "decismels" as a concentration term:

U.S. Patent No. 6,324,475 (Hayes et al.) at col. 8, lines 56-64, col. 20, lines 62-65, (and elsewhere).

Amoore and O'Neill, *Proposal for a Unifying Scale to Express Olfactory Thresholds and Odor Levels: the "Decismel Scale,"* Olfacto-Labs, Berkeley, CA (1988), in Proceedings of the 1988 Air Pollution Control Association Annual Meeting, Paper No. 78.5 (21 pp.).

The term "decismel units" is an art-recognized term that is well understood by one of ordinary skill in the odorant arts.

As for the cited references, Doty discloses a smell identification test involving 50 microencapsulated odorants for release of odorants for inhalation to establish ratings of perceived intensity, pleasantness, familiarity, coolness-warmth, and irritation (pages 3-4, bridging paragraph; Fig. 1 at page 5), and to identify individual odorants (pages 6-7, and Fig. 2). Sweeney generally disclosing microcapsules that can contain fragrance materials.

Neither of the cited references address the alteration of blood flow to the vagina of a female individual, or describe administering odorant mixtures as claimed. Accordingly, withdrawal of this rejection is respectfully requested.

Extension of Time. Applicant hereby requests a two-month extension of time to extend the time for response to **June 3, 2002**. A check in the amount of **\$200.00** is enclosed herewith to cover the extension fee. Please charge any additional fee required to Account No. 232053. Applicant is a small entity.

Based on the amendments and above remarks, it is submitted that the present claims are in condition for allowance, and notification to that effect is respectfully requested.

Respectfully submitted,



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Enclosures:

Replacement Claim Sheets
Redline version of claims showing amendments
Cited references

Replacement Claims

WHAT IS CLAIMED:

1. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant effective to alter blood flow to the vagina;

wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof.

2. (amended) The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 10-30%.

4. (amended) The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 4-15%.

5. (amended) A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina;
wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a mixture of a lavender and pumpkin pie odorant, a mixture of a baby powder and chocolate odorant, and combinations thereof.

6. (amended) A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
the odorant comprising a mixture of licorice-based and cucumber odorants; wherein
administering the odorant is effective to decrease blood flow to the vagina of the female individual by about 10-20%.

Replacement Claims

9. The method of claim 1, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.
10. The method of claim 9, wherein the concentration of the odorant is at about 25-55 decismel units.
11. The method of claim 1, further comprising: having the female individual inhale the odorant for about 1-3 minutes.
35. The method of Claim 43, whereby inhalation of the odorant increases the blood flow to the vagina by about 10-30 %.
39. The method of Claim 43, wherein the odorant is provided in a delivery device selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.
40. The method of Claim 43, wherein the odorant is provided in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.
41. The method of Claim 43, wherein the odorant is provided in the form of a cream or a cologne.
42. The method of Claim 43, wherein the odorant is provided in a liquid form contained in a dispenser.

Replacement Claims

43. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
wherein the odorant comprises a mixture of a licorice-based odorant and a cucumber odorant.

44. (amended) A method for increasing blood flow to the vagina of a female individual,
comprising:

13 administering to the female by inhalation of an odorant to increase blood flow to the
vagina by about 10-30%; wherein the odorant is selected from the group consisting of a mixture
of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber
odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and
chocolate odorants, and combinations thereof.

WHAT IS CLAIMED:

1. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant effective to alter blood flow to the vagina;

wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof.

2. (amended) The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 10-30%.

4. (amended) The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 4-15%.

5. (amended) A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina;
wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a ~~baby powder odorant~~, a mixture of a lavender and pumpkin pie odorant, a mixture of a baby powder and chocolate odorant, and combinations thereof.

6. (amended) A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
the odorant comprising a mixture of licorice-based and cucumber odorants; wherein
administering the odorant is effective to decrease blood flow to the vagina of the female individual by about 10-20%.

Redlined Claims

7. ~~The method of claim 6, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, a mixture of licorice-based and cucumber odorants, and combinations thereof.~~

8. ~~A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina;
wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, a cherry odorant, and combinations thereof.~~

9. The method of claim 1, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.

10. The method of claim 9, wherein the concentration of the odorant is at about 25-55 decismel units.

11. The method of claim 1, further comprising: having the female individual inhale the odorant for about 1-3 minutes.

24. ~~A method for altering blood flow to the vagina of a female individual, comprising:
determining a level of sexual arousal of the female individual to manual genital manipulation, to masturbation, or both; and
administering to the female individual by inhalation of an odorant to alter blood flow to the vagina.~~

25. ~~A method for altering blood flow to the vagina of a female individual, comprising:
measuring a baseline blood flow to the vagina of the female individual; and
administering to the female by inhalation of an odorant to alter blood flow to the vagina.~~

Redlined Claims

26. — A method for altering blood flow to the vagina of a female individual, comprising:
determining a level of sexual arousal of the female individual to manual genital manipulation, masturbation, or both; and
administering to the female individual by inhalation, an odorant effective to alter blood flow to the vagina compared to a baseline blood flow to the vagina without inhalation of the odorant.

27. — The method of Claim 26, whereby the level of sexual arousal to manual genital manipulation, masturbation, or both, is positive; and
the odorant is selected from the group consisting of a baby powder odorant, a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a floral-aldehydic perfume odorant, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof;
whereby the blood flow to the vagina is increased by about 10-30 %.

28. — The method of Claim 26, whereby the level of sexual arousal to manual genital manipulation, masturbation, or both, is positive; and
the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a baby powder odorant, a mixture of a lavender and pumpkin pie odorant, a mixture of a baby powder and chocolate odorant, and combinations thereof;
whereby the blood flow to the vagina is increased by about 4-15 %.

29. — The method of Claim 26, whereby the level of sexual arousal to manual genital manipulation, masturbation, or both, is positive; and
the odorant is a combination of a licorice-based odorant and a cucumber odorant.

Redlined Claims

30. — ~~The method of Claim 26, whereby the level of sexual arousal to manual genital manipulation, masturbation, or both, is negative; and~~

~~the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, a cherry odorant, a mixture of licorice-based and cucumber odorants, a floral-aldehydic perfume odorant, and combinations thereof;~~

~~whereby the blood flow to the vagina is decreased by about 10-20%.~~

31. — ~~The method of Claim 26, whereby the level of sexual arousal to manual genital manipulation, masturbation, or both, is negative; and~~

~~the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, a cherry odorant, and combinations thereof.~~

32. — ~~A method for altering blood flow to the vagina of a female individual, comprising:~~

~~measuring a baseline blood flow to the vagina of the female individual;~~

~~determining a level of sexual arousal of the female individual to manual genital manipulation, masturbation, or both; and~~

~~administering to the female individual by inhalation, an odorant effective to alter blood flow to the vagina compared to the baseline blood flow to the vagina.~~

34. — ~~The method of Claim 43, further comprising, prior to the step of administering the odorant, at least one step selected from the group consisting of:~~

~~the step of determining a level of sexual arousal of the female individual to manual genital manipulation, to masturbation, or both; the step of measuring a baseline vaginal blood flow of the female individual; and a combination thereof.~~

35. The method of Claim 43, whereby inhalation of the odorant increases the blood flow to the vagina by about 10-30 %.

38. ~~A method of altering blood flow to the vagina of a female individual, comprising:
providing an odorant to a female individual for inhalation to decrease the blood flow to
the vagina by about 10-20%;~~

~~wherein the odorant is selected from the group consisting of a licorice-based odorant, a
charcoal barbecue smoke odorant, a cherry odorant, a mixture of licorice-based and cucumber
odorants, and combinations thereof.~~

39. The method of Claim 43, wherein the odorant is provided in a delivery device selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.

40. The method of Claim 43, wherein the odorant is provided in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.

41. The method of Claim 43, wherein the odorant is provided in the form of a cream or a cologne.

42. The method of Claim 43, wherein the odorant is provided in a liquid form contained in a dispenser.

43. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
wherein the odorant comprises a mixture of a licorice-based odorant and a cucumber odorant.

44. (amended) A method for increasing blood flow to the vagina of a female individual, comprising:

administering to the female by inhalation of an odorant to increase blood flow to the vagina by about 10-30%; wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof.

45. ~~The method of Claim 44, wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof.~~

46. ~~A method of decreasing blood flow to the vagina of a female individual, comprising: administering a floral-aldehydic perfume odorant to a female individual for inhalation, whereby the blood flow to the vagina is decreased.~~

47. ~~A method of increasing blood flow to the vagina of a female individual, comprising: administering a floral-aldehydic perfume odorant to a female individual for inhalation whereby the blood flow to the vagina is increased.~~